



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2015-0508; FRL-9932-32]

Notice of a Public Meeting and Opportunity for Public Comment on Considerations for Risk Assessment of Genetically Engineered Algae

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA will be hosting a public meeting entitled, “Workshop for Public Input on Considerations for Risk Assessment of Genetically Engineered Algae” on September 30, 2015. The objective of this workshop is to receive public input and comments on EPA’s data needs to support risk assessments of biotechnology products subject to oversight under the Toxic Substances Control Act that make use of genetically engineered algae and cyanobacteria. The workshop will inform an update to an EPA guidance document entitled “Points to Consider in The Preparation of TSCA Biotechnology Submissions for Microorganisms”. EPA encourages all members of the public interested in participating in this workshop to register to attend, whether in-person or through the Web-connect and teleconference that will also be available.

DATES: *Meeting.* The workshop will be held on Wednesday, September 30, 2015, from 8 a.m. to noon, EDT.

Meeting registration. Advance registration must be completed no later than 11:59 p.m., EDT, on Friday, September 25, 2015. On-site registration will be permitted, but seating and speaking priority will be given to those who register by this deadline.

To request accommodation of a disability, please contact the workshop logistics person listed under **FOR FURTHER INFORMATION CONTACT**, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

Comments. EPA will hear oral comments on Wednesday, September 30, 2015, and accept comments and materials submitted in the docket by October 31, 2015.

ADDRESSES: *Meeting.* The workshop will be held at the Omni Shoreham Hotel, 2500 Calvert St., NW., Washington DC, 20008. The workshop will also be available via Web connect and teleconferencing for all registered participants, for further information see Unit III.A. under **SUPPLEMENTARY INFORMATION**.

Meeting registration. You may register online, by U.S. Postal Service, by

overnight/priority mail, or in person at the meeting. To register online go to <https://projects.erg.com/conferences/oppt/workshophome.htm> and complete the online registration form. To register by U.S. Postal Service or overnight/priority mail, mail your registration to: Erin Pittorino, ERG, 110 Hartwell Ave., Lexington, MA 02421.

Comments. Submit comments and materials, identified by docket ID number EPA-HQ-OPPT-2015-0508, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets in general is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Carolina Peñalva-Arana, Risk Assessment Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4816; email address: penalva-arana.carolina@epa.gov.

For workshop logistics or registration contact: Erin Pittorino, ERG, 110 Hartwell Ave., Lexington, MA 02421; telephone number: (781) 674-7260; email address: erin.pittorino@erg.com.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including those interested in environmental and human health assessment, the industrial and commercial biotechnology industry - including those employing modern versions sometimes referred to as synthetic biology, the algae production industry, chemical producers and users, consumer product companies, and members of the public interested in the assessment of biotechnology risks. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket ID number EPA-HQ-OPPT-2015-0508, is available at <http://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>. Documents and workshop information will also be available at the registration website.

C. What Should I Consider as I Prepare My Comments for EPA?

When preparing comments for EPA, whether oral or in writing, see the tips at <https://projects.erg.com/conferences/oppt/workshophome.htm> and at <http://www.epa.gov/dockets/comments.html>.

II. Background

The objective of this workshop is to discuss EPA's data needs to support risk assessments of biotechnology products subject to oversight under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.*, that make use of genetically engineered algae and cyanobacteria. The workshop will inform an update to the EPA guidance document entitled "Points to Consider in The Preparation of TSCA Biotechnology Submissions for Microorganisms".

Members of the public are invited to review the presentations and supporting documentation, including the EPA guidance document, and to provide comments on the workshop subject matter by the end of the comment period specified. This information is distributed solely for informational purposes and should not be construed to represent any Agency determination or policy. The meeting will be open to the public and experts in biotechnology, algae production, and risk assessment are encouraged to attend and present their views.

III. Meeting

A. Web Connect and Teleconferencing Access

The workshop will be available via Web connect and teleconferencing for registered participants. All registered participants will receive information on how to connect to the workshop prior to its start.

B. Public Participation at the Meeting

Members of the public may register to attend the workshop as observers and may also register to speak offering oral comments on the day of the workshop. A registered speaker is encouraged to focus on issues directly relevant to science-based aspects of the workshop and to address specific scientific points in the speaker's oral comments. Each speaker is allowed between 2–3 minutes. To accommodate as many registered speakers as possible, speakers may present oral comments only, without visual aids or written material. Given time constraints, the number of speakers allowed during the comment periods will be decided upon by the workshop chair. Speakers will be selected in a manner designed to optimize representation from all organizations, affiliations, and present a balance of science issues relevant to the workshop.

IV. How Can I Request to Participate in this Meeting?

A. Registration

To attend the workshop in person or to receive access through Web connect and teleconference, you must register no later than 11:59 p.m., on Friday, September 25, 2015, using one of the methods described under **ADDRESSES**. While on-site registration will be available, seating will be on a first-come, first-serve basis, with priority given to early registrants and until room capacity is reached. The Agency anticipates that approximately 150 people will be able to attend the workshop in person, with seating available on a first-come, first-serve basis. For registrants not able to attend in person, the workshop will also provide Web connect and teleconference capabilities.

Time permitting, on-site registrants may offer comments following those who registered earlier. For workshop logistics or registration questions contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. Required Registration Information

Members of the public may register to attend or speak if planning to offer oral comments during the scheduled public comment periods. To register for the meeting online or by mail, you must provide your full name, organization or affiliation, and contact information. If you indicate that you wish to speak, you will be asked to select one of these categories that most closely reflect the content of your oral comments: Environmental Protection, Algae/Cyanobacteria Production, Biotechnology, Biological/Genetic Engineering, Risk Assessment, Microorganisms, Ecotoxicity, Industrial Chemicals, Guidance or Other.

Authority: 15 U.S.C. 2601 *et seq.*

Date: August 18, 2015.

Wendy C. Hamnett,

Director, Office of Pollution Prevention and Toxics.

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